

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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JAMES C H, a minor,  
DIAMOND A H, a minor,  
ESTATE OF JAMES HAYDEN,  
by Karen Marie Hayden-Jefferson  
as Administrator for the Estate,

Plaintiffs,

v.

Case No. 12-C-0772

MYLAN INC.,  
MYLAN PHARMACEUTICALS INC.,  
MYLAN TECHNOLOGIES,

Defendants.

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DECISION AND ORDER GRANTING PARTIAL MOTION TO DISMISS (DOC. 6)

On August 3, 2012, defendants filed a partial motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiffs allege that James Hayden died as a result of using a defective 100 mcg fentanyl patch for chronic pain. On the other hand, defendants assert that plaintiffs' strict liability/marketing defect (count one), negligent marketing (count two), negligent misrepresentation (count three), fraud (count four), and failure to warn (count five) claims are preempted by the United States Supreme Court's ruling in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011). In addition, any claim that the defendants failed to inform the FDA, withheld information from the FDA, or otherwise committed fraud on the FDA, are impliedly preempted by federal law as set forth in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 348 (2001). In lieu of a response, plaintiff filed a proposed

stipulation of the failure to warn claims and the state law fraud on the FDA claims. For the reasons set forth below, defendants' partial motion to dismiss will be granted.

The Supremacy Clause provides that "the Laws of the United States ... shall be the supreme Law of the Land...." U.S. Const. art. VI, cl. 2. Preemption is the application of the Supremacy Clause, resulting in the rule that "any state law that conflicts with federal law is without effect." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (internal citations omitted). Express preemption occurs when Congress preempts state law by so stating in express terms. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985). Implied preemption occurs upon an inference that the state law is preempted. *Id.* A court will find implied preemption "where it is impossible for a private party to comply with both state and federal law, and where under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objections of Congress." *Crosby v. Nat. Foreign Trade Council*, 530 U.S. 363, 372–73 (2000).

In *PLIVA*, the Supreme Court found that the FDCA preempts failure-to-warn claims against generic drug manufacturers. Generic drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels, 21 C.F.R. § 314.94(a)(8)(iv) (2011), and thus cannot comply with federal labeling standards and state law requirements deviating from those standards. *PLIVA*, 131 S. Ct. at 2578.

Although not alleged in the complaint, plaintiffs do not dispute that the Mylan Fentanyl Transdermal System is a generic product approved by the FDA as the bioequivalent to Duragesic pursuant to the Abbreviate New Drug Application. Based on the clear language

of *Pliva*, the plaintiffs concede that the failure to warn claims are subject to dismissal. In addition, any state law fraud-on-the-FDA claims conflict with the medical device amendments to the Federal Food Drug and Cosmetic Act. *Buckman Co.*, 531 U.S. at 350-352. Consequently,

IT IS ORDERED that counts defendants' partial motion to dismiss is granted.

IT IS FURTHER ORDERED that the marketing defect claim asserted in count one (paragraph 28) is dismissed.

IT IS FURTHER ORDERED that the negligent failure to warn claims asserted in count two (paragraphs 33(a), (n), and (q)) are dismissed.

IT IS FURTHER ORDERED that the negligent misrepresentation claim asserted in count three is dismissed.

IT IS FURTHER ORDERED that the fraud claim asserted in count four is dismissed.

IT IS FURTHER ORDERED that the failure to warn claim asserted in count five is dismissed.

IT IS FURTHER ORDERED that the punitive damages claim asserted in count six is dismissed to the extent it is predicated on a fraud and/or failure to warn theory.

Dated at Milwaukee, Wisconsin, this 13th day of November, 2012.

BY THE COURT

/s/ C. N. Clevert, Jr.  
C. N. CLEVERT, JR.  
U. S. DISTRICT JUDGE